



www.ddcvalidation.com
(877) cGMP-211

Cleaning Validation

D & D Consulting LLC provides world class cleaning validation and development services to pharmaceutical and biotech companies. Our consultants have performed cleaning validation and development for bioreactors, tanks, filling machines, glassware washers, hoses and many other various systems. We offer a high quality standard for the following areas:

- **Cleaning Validation Master Plans**
- **Test Method Development and Validation**
- **Swab and Rinse Recovery Studies**
- **Visual Inspection Studies**
- **Design-of-Experiments (DOE)**
- **Wash-out-Curves**
- **Cycle Development**
- **Protocol Development and Execution.**
- **Monitoring Programs**



Pharmaceutical products and active pharmaceutical ingredients (APIs) can be contaminated by other pharmaceutical products, by cleaning agents, micro organisms (and their components), or by other materials.

Cleaning Validation provides the documented evidence that ensures your approved cleaning and storage procedures provide the removal of residues to predetermined levels. The FDA's "Guide to Inspection of Bulk Pharmaceutical Chemicals" and the "Biotechnology Inspection Guide" are designed to establish inspection consistency and uniformity for cleaning validation program.

Today, many companies have an incomplete/lack robust detection method, rationale to address cleaning validation, and/or a lack of a monitoring program once their cleaning validation is complete and are therefore seeking D & D Consulting LLC to help them develop/improve their cleaning validation methods and procedures.